September 2014 Montana DUR Board Meeting Minutes

Date: September 17, 2014
Members Present: Lisa Sather, Caldwell, Bradley, Burton, Brown, Harrison, Putsch, Crichton
Others Present: Dave Campana, Katie Hawkins and Dan Peterson from Medicaid, Woodmansey, Doppler, Barnhill Drug Case Management, and representatives of drug manufacturers.
Lisa Sather opened the meeting.
Public Comment:
There was no public comment.
Meeting Minute Review:
Meeting minutes from April were approved.
Department Update:
Dave Campana gave the Board the following update:
Effective July 1, the Department implemented a new preferred drug / preferred generics/ other generics dispensing fee of $ 6.65.
On July 29, the Department implemented the short-acting oxycodone maximum units per month of 240 tablets for 30 days.
The Department has sent out the next dispensing fee survey which pharmacies need to be sure to complete and return to get their highest dispensing fee possible. Failure to complete this survey will result in the pharmacy receiving a $ 2.00 dispensing fee.
On August 25, the Department re-implemented the vaccine administration program for pharmacy claims. This will pay $21.32 for the first vaccine, and $12.68 for subsequent vaccines administered the same day.

Board Discussion

PDL follow-up item

During the March preferred drug list meeting, the Board reviewed the previous and current quinolone recommendations. The request was made for more information on quinolone resistance patterns in Montana. Angie Woodmansy reported on the most current information available from the State of Montana and from St. Peter's Hospital.

Criteria Updates:

Kalydeco® recommended criteria updates due to expanded indications for additional CFTR gene mutations:

- Patient must be 6 years of age or older.
- Patient must have confirmed G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, or G1349D mutation as detected by an FDA-cleared CF mutation test.
- Dosing will be limited to a maximum of 2 tablets daily.

New criteria approved by the Board.

Oral anticoagulant criteria updates due to new indications:
Eliquis® (apixaban) new indication for DVT prophylaxis and treatment of PE/DVT. Recommended additions to current criteria:

For DVT prophylaxis-No previous therapy required.
LIMITATIONS:

- Max 2.5 mg twice daily
- Hip replacement-max 35 days
- Knee replacement-max 12 days

For Treatment of PE/DVT-pt must have ADR/contraindication to warfarin or LMWH
LIMITATIONS:

- Max 10 mg twice daily x 7 days, then 5 mg twice daily thereafter

For Reduction in risk or recurrence of PE/DVT- pt must have ADR/contraindication to warfarin or LMWH
LIMITATIONS:

- Max 2.5 mg twice daily after 6 months of treatment for PE/DVT

Pradaxa® (dabigatran) new indication for treatment of PE/DVT/Reduction in risk or recurrence of PE/DVT. Recommended additions to current criteria:

Patient must have ADR/contraindication to warfarin
LIMITATIONS:

- Max dose allowed will be 150 mg twice daily in patients with CrCl >30 mL/min.
- Approval will not be granted if CrCl<30 mL/min or patient on dialysis
- Approval will not be granted if CrCl<50 mL/min with concomitant P-gp inhibitors

Criteria additions for oral anticoagulants were discussed and approved.

Xolair® recommended criteria update due to new indication for chronic idiopathic urticaria:

The Board discussed the place in therapy for this medication for chronic idiopathic urticaria. Case management will discuss specific recommendations with the allergy specialist who has experience with this medication. These recommendations will be returned to the next meeting.

Dronabinol dose limits and dose per day limit recommendations:

- Maximum daily dose of 20mg daily
- Maximum quantity for 2.5mg and 5mg capsules of 4 doses daily, and for 10mg capsules 2 doses daily.
- During chemotherapy induced nausea flares, these limits may be suspended.

Daily dose and maximum quantity limits for dronabinol were discussed and approved.

Growth Hormone products-safety warning:

Dave Campana presented a study to the Board that discussed an increased risk of stroke in some patients on growth hormone. The study contended that patients who were using growth hormone for a diagnosis of short stature were at an elevated stroke risk. The Board discussed our current policy of non-coverage of growth hormone for short stature. Dan Peterson from DPHHS reminded the Board of the definition of "medically necessary" and the ability of the State to cover medications based only on this determination. No new recommendations were made.

New Criteria Development:

The following criteria was discussed and approved by the DUR Board.

Zohydro ER® Clinical Criteria Requirements

- Patient must be 18 years of age or older.
- Patient has a diagnosis of severe chronic pain with documented objective etiology requiring around the clock opioid management
- Dosing limited to q 12 hours
- Patient has had a trial or contraindication to all preferred agents (currently Fentanyl, MS ER) AND
- Patient has had a trial or contraindication to Oxycontin®
- Coverage not authorized for:
    - Acute or intermittent pain
    - Immediate post-surgical pain
    - Use in patients who require opioid analgesia for a short period of time or as needed pain relief
- Initial approval for 3 months for non-malignant pain. Treatment plan may be required for continued authorization. 1 year approval for cancer pain.

Hetlioz® Clinical Criteria Requirements

- Prescriber must be a sleep specialist or patient must have a current specialty consult (within the previous year).
- Patient must have a diagnosis of FRD (Free-running Disorder)
- Patient must be blind
- Patient must have documented functional impairment due to FRD
- Other therapies (timed melatonin or planned social/physical activities) must have been inadequate for improving functional impairment.
- Prior authorization will be granted for a maximum daily dose of 20 mg and an initial period of 6 months.

Lovaza®/Vascepa®Clinical Criteria Requirements

- Patient must have a triglyceride level $\geq$500 mg/dl AND
- Patient has had a documented trial of a preferred fibric acid product (e.g. gemfibrozil, Trilipix®, Tricor®) or preferred niacin product (e.g. Niaspan®)
- Dosing will be limited to 4 grams daily

IBS Agents (Amitiza®, Linzess®, and Lotronex®) Clinical Criteria Requirements

Amitiza®

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of Chronic *Idiopathic Constipation, Opioid-induced constipation, or Irritable bowel syndrome.*
- Treatment for chronic idiopathic constipation and Opioid-induced constipation will be limited to 24mcg with a maximum daily dose of 2 capsules.
- Patients with IBS must be female and are approved for 8mcg with a maximum daily dose of 2 capsules.
- Patient must not currently be taking methadone.
- Patient must have been unsuccessful with documented treatment with appropriate over the counter laxatives.

Linzess®

- Patient must be > 18 years of age.
- Patient must have a diagnosis of Chronic Idiopathic Constipation, or Irritable Bowel Syndrome with constipation.
- Treatment for chronic idiopathic constipation will be approved for 145mcg with a maximum daily dose of 1 capsule.
- Treatment for Irritable Bowel Syndrome with Constipation will be approved for 290mcg with a maximum daily dose of 1 capsule.
- Patient must have been unsuccessful with documented treatment with appropriate over the counter laxatives.

Lotronex®

- Patient must be female.
- Patient must have a diagnosis of Chronic Irritable Bowel Syndrome with diarrhea.
- Maximum daily dose of 2 tablets.
- Patient must have had an unsuccessful trial on loperamide.

Hepatitis C Discussion:

Angie Woodmansey updated the Board on the Hepatitis C pharmacy case management program. She discussed the current number of active cases, denials, completions, successes and failures in this program. All patients are on Solvaldi® for Hep C treatment. Some patients are on Olysio® in addition to Solvaldi®, while others are on ribavirin and/or peg-interferon with Solvaldi®. New agents are being prepared to be launched. This discussion prompted a renewed discussion on patient readiness to treat. The board strongly recommended inclusion of an assessment of patient readiness into the current clinical criteria. Case management will pursue additional specialist input on this issue and return to the board.

The PA criteria for Hepatitis C medications will remain the same with the addition of the requirement for prospective providers to present patient chart notes with PA requests. The criteria will be revisited as new guidelines are released and newer medications gain approval by the FDA.

Executive Session:

The Board discussed case sensitive issues in a closed session.

The next meeting is scheduled for October15, 2014 at MPQH office building.
Meeting adjourned at 3:55.